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09/599,269	06/22/2000	Stephen W. Rose	OF-102US	8360

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EXAMINER
OCAMPO, MARIANNE S

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/599,269	Applicant(s) ROSE ET AL.	
	Examiner Marianne S. Ocampo	Art Unit 1723	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,9-15,17-25,27 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,9-15,17-25,27 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 – 4, 6 – 7, 9 – 13, 22- 23 and 29 - 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gsell et al. (US 5,258,127) in view of Marshall et al. (WO 98/07905).

3. With regards to claim 1, Gsell et al. disclose a pleated filter cartridge (36) for removing particulates (such as leucocytes & other deleterious matter such as fat emboli, microaggregates, lipids & other debris) from a liquid (such as blood & other biological fluids), the pleated filter cartridge being of the type including a perforated core (55), a pair of end caps (56 & 57) and an annular non-woven (unwoven) filter element (53, 36) around the core formed by substantially axially-parallel pleats (i.e. pleated form) of at least one sheet of filter material (53), the filter element having opposite ends each in sealing engagement with one of the end caps (56, 57), characterized in that the porous filter material (53) being a *non-perforated* (this term

has been defined by the examiner to mean it has not been punched/stamped or pierced to create holes or pores or openings therethrough), non-woven (unwoven) fibrous material of polyethylene terephthalate, and the porous material (53) having an annular thickness of 0.25 cm (2.5 mm) to 7.62 cm (76.2 mm) and has a filtration efficiency of 99.7% in removing leucocytes (which are micronic size particulates), as in cols. 1 – 11 and in fig. 1. Gsell et al. fail to disclose the non-woven filter material being flash-spun plexifilamentary high-density polyethylene fibrils having a thickness of less than about 0.15 mm, a pressure drop of less than 4 psid at a flow rate of 10 gal/hr and a filtration efficiency of at least 98% of 1-2 micron particulates at a pressure differential of 30 psid. Marshall et al. teach a porous non-perforated, non-woven filter material for use as a filter element (in microfiltration applications for removing suspended solids and other very small micronic size matter), similar to that of Gsell et al, the filter material of Marshall et al. being flash-spun plexifilamentary high-density polyethylene fibrils having a permeability which causes a pressure drop of less than 4 psid at a flow rate of 10 gal/hr and a filtration efficiency of 99% of 1-2 micron dust particulates at a pressure differential of 30 psid., and has at least one embodiment (examples 27, 29 - 32) having a thickness of at least 122 microns (0.122 mm) to 144.5 microns (0.145 mm), which is less than about 0.15 mm, as in the abstract and in page 3 of WO (905) & pages 25 - 27. It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the pleated filter cartridge of Gsell et al., by substituting the filter material of the cartridge of Gsell et al, in lieu of the filter material taught by Marshall et al., in order to provide an alternative and improved filter material for the cartridge which has improved ability to remove very small micronic size range particulates in sizes of 1 –

2 mcirons at an efficiency of at least 99% as well as good barrier and strength properties and does not require laminations or other support structures [see pages 1 – 10 of Marshall et al./WO (905)].

4. Concerning claim 2, Gsell et al. as modified by Marshall et al. further teach the filter material (resulting from the combination of teachings of both prior art), particularly those of *examples 30 – 31 which have a pressure drop of 1.3 and 1.0 psid, respectively, at a flow rate of 10 gal/hr (see table 5 in page 27) and a filtration efficiency of 99.98% and 99.95%, respectively, of 1 – 2 microns at a pressure differential of 30 psid*, having a pressure drop of less than about 1.5 psid at a flow rate of 10 gal/hr and a filtration efficiency of at least about 99% of 1 – 2 microns at a pressure differential of 30 psid, as in page 27 of WO (905). The same motivation applied in claim 1 above, is being applied here.

5. Regarding claims 3 - 4, Gsell et al. as modified by Marshall et al. further teach the filter material (resulting from the combination of teachings of both prior art), in particular that of *example 31 which has a mean flow pore size of 5.935 microns and a Gurley Hill porosity rating of 3.57 seconds/100cc*, having a mean flow pore size greater than 4 microns (claim 3) and a Gurley Hill porosity rating no greater than about 5 sec/100cc (claim 4), as in table 5, page 27 of WO (905). Regarding the nominal pore-size filtration rating of 1 micron (claim 3), since the filter material being claimed by the invention is the same material taught by Marshall et al (see pages 8 – 9 of the original specification)., it is considered inherent that the filter material

resulting from the combination of teachings of Gsell et al. and Marshall et al. would also have a nominal pore-size filtration rating of 1 micron.

6. Concerning claim 6, Gsell et al. as modified by Marshall et al. also teach the filter material (resulting from the combination of teachings of both prior art), particularly those *examples 27 and 30 which have a thickness of 122 microns (0.122 mm) and 128 microns (0.128mm), respectively*, having a thickness less than or equal to about 0.13 mm, as in pages 26 – 27 of WO (905).

7. With respect to claim 7, Gsell et al. as modified by Marshall et al. further teach the filter material (resulting from the combination of teachings of both prior art), in particular that of *example 31 which has a basis weight of 42.7 g/m^2*, having a basis weight of less than about 45 g/m^2.

8. Regarding claim 9, Gsell et al. as modified by Marshall et al. also teach the filter material (resulting from the combination of teachings of both prior art), particularly those *examples 27 and 30 which have a thickness of 122 microns (0.122 mm) and 128 microns (0.128mm), respectively*, having a thickness less than or equal to about 0.13 mm, as in pages 26 – 27 of WO (905).

9. With regards to claim 10, Gsell et al. also disclose the filter element (36) having at least two layers including a mesh layer (screen, 54) with the filter material (53), as in fig. 1 and col. 6, lines 8 – 12.

10. Concerning claim 11, Gsell et al. further disclose the mesh layer (screen, 54) being between the filter material (53) and the core (55), as in fig. 1.

11. With respect to claim 12, Gsell et al. also disclose a single layer of the filter material (53) serving as a sole filtering layer, as in fig. 1 and in cols. 3 – 7.

12. Regarding claim 13, Gsell et al. disclose the mesh layer (54) being formed of any compatible porous membrane or woven or non-woven mesh or screen to that of the pleated filter medium (53), which includes low-density polyethylene (which would be at least compatible with polyethylene teraphthalate or any polyethylene filter medium), as in col. 6, lines 19 – 25. It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the mesh layer from any compatible porous non-woven mesh or screen to particularly that of a low density polyethylene mesh in order to provide a suitable material of construction which has desirable properties appropriate for the filtration conditions that the filter cartridge of Gsell et al. as modified by Marshall et al. would be exposed to. In particular, low-density polyethylene is well known for its good temperature resistance and good impact and tensile strength (see

Hawley's Condensed Chemical Dictionary, 13th ed., page 898 for properties of low-density polyethylene).

13. With regards to claim 22, Gsell et al. further disclose a single layer of the filter material (53) serving as a sole filtering layer, as in fig. 1 and in cols. 3 – 7.

14. Concerning claim 23, Gsell et al. disclose an annular pleated filter element (36, 53) for removing particulates (such as leucocytes & other deleterious matter such as fat emboli, microaggregates, lipids & other debris) from a liquid (such as blood & other biological fluids), formed by substantially axially-parallel pleats (i.e. pleated form) of at least one sheet of filter material (53) and a mesh layer (54), wherein the filter material (53) being a *non-perforated* (this term has been defined by the examiner to mean it has not been punched/stamped or pierced to create holes or pores or openings therethrough), non-woven (unwoven) fibrous material of polyethylene terephthalate, and the porous material (53) having an annular thickness of 0.25 cm (2.5 mm) to 7.62 cm (76.2 mm) and has a filtration efficiency of 99.7% in removing leucocytes (which are micronic size particulates), as in cols. 1 – 11 and in fig. 1. Gsell et al. also disclose the mesh layer (54) being formed of any compatible porous membrane or woven or non-woven mesh or screen to that of the pleated filter medium (53), which includes low-density polyethylene (which would be at least compatible with polyethylene teraphthalate or any polyethylene filter medium), as in col. 6, lines 19 – 25. Gsell et al. fail to disclose the non-woven filter material being flash-spun plexifilamentary high-density polyethylene fibrils having a thickness of less

than about 0.15 mm, a pressure drop of less than 4 psid at a flow rate of 10 gal/hr and a filtration efficiency of at least 98% of 1-2 micron particulates at a pressure differential of 30 psid.. Marshall et al. teach a porous non-perforated, non-woven filter material for use as a filter element (in microfiltration applications for removing suspended solids and other very small micronic size matter), similar to that of Gsell et al, the filter material of Marshall et al. being flash-spun plexifilamentary high-density polyethylene fibrils having a permeability which causes a pressure drop of less than 4 psid at a flow rate of 10 gal/hr and a filtration efficiency of 99% of 1-2 micron dust particulates at a pressure differential of 30 psid., and has at least one embodiment (examples 27, 29 - 32) having a thickness of at least 122 microns (0.122 mm) to 144.5 microns (0.145 mm), which is less than about 0.15 mm, as in the abstract and in page 3 of WO (905) & pages 25 - 27. It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the pleated filter cartridge of Gsell et al., by substituting the filter material of the cartridge of Gsell et al, in lieu of the filter material taught by Marshall et al., in order to provide an alternative and improved filter material for the cartridge which has improved ability to remove very small micronic size range particulates in sizes of 1 – 2 microns at an efficiency of at least 99% as well as good barrier and strength properties and does not require laminations or other support structures [see pages 1 – 10 of Marshall et al./WO (905)].

15. With respect to claim 29, Gsell et al. as modified by Marshall et al. also teach the filter material (resulting from the combination of teachings of both prior art), particularly those *examples 27 and 30 which have a thickness of 122 microns (0.122 mm) and 128 microns*

(0.128mm), respectively, having a thickness less than or equal to about 0.13 mm, as in pages 26 – 27 of WO (905).

16. Regarding claims 30 - 31, Gsell et al. as modified by Marshall et al. also teach the filter material (resulting from the combination of teachings of both prior art), being a single sheet or layer of filter material (i.e. does not require support structures such as an additional screen or mesh layer) which has, particularly those *examples 27 and 30 which have a thickness of 122 microns (0.122 mm) and 128 microns (0.128mm), respectively*, a thickness less than or equal to about 0.13 mm, thereby making the total thickness of the filter material being less than about 0.15 mm, as in pages 26 – 27 of WO (905).

17. Claims 18 - 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gsell et al. and Marshall et al., as applied to claims 1 and 10 above, and further in view of Pall (US 4,033,881) and Hawley's Condensed Chemical Dictionary (Lewis, Sr., Richard J., 13th edition).

18. Concerning claims 18 and 20, Gsell et al. as modified by Marshall et al., fail to teach the filter cartridge further including a containment sleeve of polyethylene netting enclosing the annular filter element. Pall (881) teaches a pleated filter cartridge (10) for removing particulates from a liquid, similar to that of Gsell et al, in which the cartridge comprises a perforated core (14), a pair of end caps (16 & 17) and an annular non-woven filter element (12) formed by substantially axially-parallel pleats of at least one sheet of filter material and the filter element

having opposite ends each in sealing engagement with one of the end caps (16, 17) as in figs. 2 – 3, wherein the filter material (12) being a non-perforated, non-woven material of fibrous sheet of polyethylene and/or other synthetic resinous materials (col. 3, lines 16 – 22) and furthermore, the cartridge (10) including a containment sleeve (13) of (extruded/nonwoven) polyethylene netting enclosing the annular filter element (12), as in cols. 3 – 4. It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the filter cartridge of Gsell et al as modified by Marshall et al, by adding the embodiment (a containment sleeve of polyethylene netting) taught by Pall, in order to provide an improved filter cartridge having the means or structure to provide additional prefiltering or rigid (stable) support to the filter element of the cartridge which helps in withstanding encountered differential pressures across the filter element and increase lifespan of the filter cartridge (see cols. 3 – 4 of Pall).

19. Regarding claims 19 and 21, Gsell et al. discloses the core (55) and the end caps (56, 57) being made of polymeric material, as in col. 6, lines 34 – 42. It is well known in the art that polymeric materials include polyethylene. Pall further teaches the end caps (17, 16) and the core (i.e. internal support 14) being formed of a thermoplastic material, in particular that of polyethylene, as in col. 4, lines 58 – 66 of Pall. It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the material of construction of the core and end caps of the cartridge of Gsell et al., as modified by Marshall et al. by changing the material from any polymeric material to specifically polyethylene, because of its desirable properties including high temperature resistance, excellent resistance to chemicals and high impact and tensile

strength. (See also Hawley's Condensed Chemical Dictionary, page 897 for properties of polyethylene). The case law ***In re Leshin***, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) stated that a prima case of obviousness exists in a selection of a known plastic/*polymer* (i.e. polyethylene) to make a container of a type made of plastics/*polymer* prior to the invention.

20. Claims 14 – 15, 17, 24 – 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gsell et al. and Marshall et al., as applied to claims 13 and 23 above, and further in view of the article "Ethylene Polymers, LDPE" (*Encyclopedia of Polymer Science and Technology*, copywright 2002 by John Wiley & Sons, Inc., article online posting date, Oct. 22, 2001, pages 1 - 12), article "Ethylene Polymers, HDPE", polymer structure and properties of HDPE section (*Encyclopedia of Polymer Science and Technology*, copywright 2002 by John Wiley & Sons, Inc., article online posting date, Oct. 22, 2001, pages 1 – 6), and Miller et al. (US 5,252,207).

21. With regards to claims 14, 17, 24 and 27, although Gsell et al. as modified by Marshall et al. do not teach explicitly the softening temperature ranges of both high density polyethylene (HDPE) filter material and of the (low density) polyethylene mesh (LDPE) layer, it is considered known in the art that these polymeric materials have softening temperature ranges and that the LDPE mesh layer would have a softening temperature range lower than the lower end of the softening temperature range of the HDPE filter material, but Gsell et al. as modified by Marshall et al. fail to teach the low-density polyethylene mesh being tack-point connected to

the HDPE filter material without having compromised the (HDPE) filter material. The article "Ethylene Polymers, LDPE", teaches low density polyethylene (LDPE) materials which can be used as the (polyethylene) mesh layer of Gsell et al. as modified by Marshall et al., having a softening temperature in the range of 90 – 93 °C, which is about 194 to 199 °F, as in page 3 of the physical properties section of the article. It is known in the art that high density polyethylene (also known as HDPE, in which the TYVEK filter material comprised thereof) having a softening temperature range of 126 – 133 °C, equivalent to 258.8 – 271.4 °F, as in page 2 of the article, "Ethylene Polymers, HDPE", polymer structure and properties of HDPE section mentioned above. The softening temperature range of LDPE of 90 – 93 °C, which is about 194 to 199 °F, is lower than the lower end value of 126 °C (258.8 °F) of the softening temperature range of HDPE filter material (i.e. TYVEK), and within the claimed range of 170 – 195 °F (claims 17 & 27).

22. Miller et al. (207) teach a pleated filter cartridge comprising a perforated core (11), a pair of end caps (12, 13) and an annular non-woven filter element (20) around the core (11) formed by substantially axially parallel pleats of at least one sheet of filter material (23) and the element having opposite ends each in sealing engagement with the end caps (12, 13), similar to the pleated filter cartridge of Gsell et al. as modified by Marshall et al., and the filter element of Miller et al. having a polymeric mesh layer (drainage/downstream support layer 24) between the at least one sheet of filter material (23) and the core (11) and the polymeric mesh layer (24) being tack point connected (i.e. the netting/mesh 24 being bonded at various points on the filter

layer 23 by beads of polymeric resin 25) without having compromised the filter material (23), as in fig. 2, 4 - 5 and in cols. 3 – 8 and 12. It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the filter cartridge of Gsell et al, as modified by Marshall et al, and articles, "Ethylene Polymers, LDPE" and "Ethylene Polymers, HDPE", by adding the embodiment taught by Miller et al., in order to provide an improved pleated filter cartridge which has materials which have desirable filtration properties including thermal and chemical resistance and good impact and tensile strength to provide a more durable and stable filter cartridge, as well as provide a filter cartridge which has the additional support means or structure to add stability to the filter material during use, without restricting flow of fluid therethrough (see col. 6 of Miller et al.).

23. Regarding to claims 15 and 25, Miller et al. further teach the mesh layer (24) and the filter material being tack-point connected (bonded at selected points of the mesh layer to the filter material) prior to pleating (i.e. prior to being fed to a corrugator which forms the pleats to form a pleated filter cartridge), as in cols. 6 – 7 and particularly in col. 7, lines 33 – 49. The same motivation applied to claim 14 above is applied here. Claim 15 is a product by process claim. The patentability of a product by process claim is based upon the product itself, eventhough the claim is limited and defined by process (in this instance, *tack-point connecting the filter material to the mesh layer prior to pleating*), and therefore, the product in such a claim is unpatentable if it is the same as, or obvious from the product of the prior art, even if the product of the prior art had been made by a different process. *See* ***In re Thorpe****, et al., No. 85-*

1913 (11-21-85) 227 USPQ pages 964 – 966. The examiner has considered that the teachings of the prior art, Gsell et al. as modified by Marshall et al., Ethylene Polymers articles mentioned above and Miller et al., together as a whole, teach at least an obvious variant of the claimed invention, if not the same product being claimed as the invention.

Response to Arguments and Amendments

24. Applicant's amendments and arguments filed on 2-7-03 with respect to claims 1- 4, 6 – 7, 9 – 15, 17 – 25, 27 and 29 - 31 have been considered but are moot in view of the new grounds of rejection based on the newly found art, Gsell et al, in combination with previously applied art, Marshall et al. (WO 905), Hawley's Condensed Chemical Dictionary, Ethylene Polymers articles and Miller et al. (207).

25. Previous rejections based on 35 USC 112 have been withdrawn in light of the amendments and persuasive arguments filed on 2-7-03. Arguments regarding to previously applied prior art, Stoyell et al. and Miyagi et al. have been withdrawn and therefore are now moot. **This action is non-final.**

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 4,154,688 (Pall).

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne S. Ocampo whose telephone number is (703) 305-1039. The examiner can normally be reached on Mondays to Fridays from 8:00 A.M. to 4:30 P.M..

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on (703) 308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

29. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

M.S.O.
May 5, 2003

W. L. WALKER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700